

EXHIBIT C

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P., et al.,*
Case No. 18-op-45090

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

*The County of Cuyahoga, Ohio, et al. v.
Purdue Pharma L.P., et al.,*
Case No. 17-op-45004

GIANT EAGLE'S NOTICE REGARDING PHARMACIST TRIAL WITNESSES

Defendants Giant Eagle, Inc. and HBC Service Company (together, “Giant Eagle”) submit this notice in response to the Court’s directive to Defendants in its Order dated April 29, 2020 (Doc. # 3280) (the “**Order**”) to provide early disclosure of their pharmacist trial witnesses.¹ Giant Eagle objects to the Order on multiple grounds: (1) it prematurely and unfairly alters the procedures and deadlines already set out by the Court in its pretrial order, *see* Doc #3234; (2) it contemplates full-blown dispensing data discovery as the price for calling pharmacy witnesses previously identified in Track 1A²; and (3) it provides Plaintiffs with an unfair opportunity to

¹ The Order states: “[D]efendants shall submit a notice identifying a small number of pharmacist witnesses whom they actually intend to call at trial. Defendants shall provide each pharmacist’s name, store number, period of employment, and a brief description of their testimony. Defendants shall also explain: why that testimony is necessary; whether other, non-pharmacist witnesses can supply some or all of that testimony; and why the pharmacist’s testimony is appropriate if that pharmacist was not involved in suspicious order due diligence or SOMS review when it occurred. Finally, Defendants shall explain the extent to which plaintiffs should be allowed to call pharmacist witnesses, and why.”

² The Sixth Circuit repeatedly emphasized in its recent Mandamus Opinion that discovery in the distribution case was “closed” and “complete” ten months prior to the stricken dispensing amendments. *See* Doc #3263 at 3-8 (the “Mandamus Opinion”).

retroactively repair serious defects in their closed distribution case, including their lack of an expert with respect to Giant Eagle’s purported liability. When Plaintiffs successfully moved to sever Giant Eagle and four other Pharmacy Defendants from the Track 1A trial last August, they represented that severed Defendants would suffer no prejudice. But that promise will be rendered entirely illusory if Plaintiffs are allowed to reopen discovery merely because some Pharmacy Defendants wish to defend themselves by calling pharmacists identified from the outset in Track 1A.

Based on extensive disclosures, document productions, and depositions before severance, Plaintiffs have always known that Giant Eagle plans to rely upon the testimony of management-level and store-level pharmacists to support its defense. From Day 1 Giant Eagle has maintained that its integrated control systems, in place at its corporate offices, self-distribution warehouse, and pharmacies, complied at all times with the DEA’s main Security Regulation, 21 C.F.R. §1301.71 (the “Security Regulation”). The Security Regulation requires all registrants to “provide effective controls and procedures to guard against theft and diversion of controlled substances” and substantial compliance with this regulation is based in part upon the security requirements in §§1301.72-1301.76 (including the distributor-only requirement in §1301.74(b) to have a “system to disclose to the registrant suspicious orders of controlled substances” and the “Know Your Customer” policy) based on an “evaluation of the overall security system and needs of the applicant or registrant.” That evaluation, in turn, is based upon the individual facts of the registrant, including the type, quantity and form of controlled substances handled, location of the premises, type of building and secure enclosures, and the adequacy of key control systems and the system for monitoring the receipt, distribution and disposition of controlled substances in its operations, *see* §1301.71(b). As these regulations make clear, Giant Eagle’s “overall security

system” determines compliance with the Security Regulation, and that system must be evaluated in part based upon the fact that the HBC warehouse only self-distributed³ one (1) opioid at issue (hydrocodone combination products, such as generic Vicodin) from November 2009 until it was reclassified as a Schedule 2 controlled substance in October 2014.

Against this regulatory background, the jury can reasonably evaluate Giant Eagle’s “overall security system,” including its “system for monitoring the receipt, distribution and disposition of controlled substances,” with testimony from store-level pharmacists that actually placed the orders to the HBC warehouse, including why such orders were appropriate and not “suspicious.” In addition to store-level controls, Giant Eagle’s overall security system includes: (1) management-level pharmacy district leaders who, although licensed and experienced pharmacists, no longer dispense pharmaceuticals and are instead responsible for overseeing multiple stores in a geographic region, and (2) corporate-level management pharmacists who also no longer dispense and exercise oversight and control over purchasing, inventory, and internal controls at the warehouse and pharmacies. **Importantly, none of these pharmacists will testify about any specific prescription, except possibly in rebuttal if Plaintiffs are permitted to use dispensing data.** Instead, they will focus on their role in Giant Eagle’s integrated system of controls.

Plaintiffs were well aware of Giant Eagle’s integrated controls defense because they were disclosed in discovery responses, documents, and deposition testimony. On top of that, Plaintiffs extensively questioned numerous Giant Eagle witnesses about this subject. *See, e.g.,* Depositions of J. Tsipakis, G. Carlson. J. Millward, and W. Durr. And, given that Giant Eagle

³ Giant Eagle’s distribution warehouse filled orders only from Giant Eagle pharmacies and therefore knew its customers at all times.

identified these witnesses in Track 1A discovery responses, the Court should not rescue Plaintiffs from their strategic decisions to focus their attention elsewhere in their Track 1A discovery.

Procedural Posture and Closed Track 1A Discovery

The Order was prompted by Plaintiffs' Position Statement Regarding Track One-B Discovery And Case Management, dated April 27, 2020 ("Plaintiffs' Position Statement"), and related argument at the April 28, 2020 status conference. Though the Sixth Circuit took dispensing date out of Track 1B, Plaintiffs improperly seek to leverage their non-use of dispensing data (which they should have never received per the Sixth Circuit's Mandamus Opinion, Doc #3262), into obtaining a strategic benefit in their closed distribution case:

[P]laintiffs will agree that no dispensing related discovery ordered produced after November 19, 2019, may be used in the Track One-B trial if Defendants confirm that they will not call any pharmacists or present or rely on any dispensing related evidence at trial. If Defendants stipulate to this limitation, Plaintiffs will also agree to the schedule Defendants have proposed, with one minor addition discussed below. If, however, Defendants intend to present or rely on any dispensing related evidence, then the Plaintiffs must be permitted to counter with the dispensing evidence, including that which was produced since amendment (and is still owed to Plaintiffs).

See Plaintiffs' Position Statement at 2. In other words, Plaintiffs agree not to use Defendants' dispensing data that they improperly obtained only IF Defendants agree to give up calling their own pharmacists to defend themselves in the remaining distribution case.

The Hobson's choice Plaintiffs have offered the Pharmacy Defendants attempts to link entirely unrelated concepts and ignores the history of discovery in the distribution case. That discovery—which closed many months ago—led to the severance of most of the Pharmacy Defendants (including Giant Eagle) in mid-August of 2019. If they have their way, Plaintiffs will gain an improper and prejudicial strategic advantage in their closed distribution case merely because they fortuitously obtained the dispensing data before the Sixth Circuit ruled that their dispensing claims should not have been allowed in the first place.

Plaintiffs readily admit, as they must, that during Track 1A discovery they were aware of Giant Eagle’s reliance on its pharmacists and internal control documents to defend its distribution practices. *See* Plaintiffs’ Position Statement at 2. Giant Eagle’s discovery responses clearly identified pharmacists and other employees, and Plaintiffs requested and received custodial documents from multiple pharmacists. In response to Plaintiffs’ distribution interrogatory asking Giant Eagle to “identify all Persons who were responsible for administering, overseeing, developing, and/or implementing any and all policies, procedures, systems or programs designed to detect and report Suspicious Orders or to maintain effective controls against diversion of Controlled Substances for January 1, 1995 to present” Giant Eagle provided a list of 27 individuals, many of whom are pharmacists, and further disclosed that “Pharmacists at Giant Eagle pharmacies in the Track One jurisdictions (as disclosed in deposition testimony)” also had such responsibilities including, as examples, four (4) named pharmacists.⁴ And, Plaintiffs even sought and obtained an order in Track 1A requiring Giant Eagle to produce certain dispensing discovery including dispensing policies, pharmacist compensation policies, and a 30(b)(6) witness on these issues. *See* Doc #1055. Thus, there can be no dispute that now-closed Track 1A discovery included multiple disclosures by Giant Eagle that showed it would rely upon pharmacists to testify about dispensing policies and controls (but not dispensing data).

Given this history, it would be highly prejudicial to Giant Eagle and the other Pharmacy Defendants for this Court to give Plaintiffs another chance to take depositions that they chose to

⁴ See HBC Service Company’s Supplemental Answers to Plaintiffs’ First Set of Interrogatories To HBC Service Company dated March 4, 2019 at 30-35, and HBC Service Company’s Second Supplemental Answers to Plaintiffs’ First Set of Interrogatories To HBC Service Company dated March 29, 2019 at 29-35. Identical disclosures were made in response to Plaintiffs’ interrogatory seeking the identify of any person “who likely has discoverable information that tends to support a position or defense that You have taken or tend to take in this action”. *Id.* Plaintiffs never sought any further information regarding individuals described in Giant Eagle’s responses, although Plaintiffs fully explored Giant Eagle’s pharmacy-level policies and procedures during their thirteen (13) depositions of Giant Eagle employees including multiple pharmacists.

forego in Track 1A. For precisely this reason, Special Master Cohen denied Plaintiffs' request in Track 1A to take depositions of pharmacists that they chose not to depose during discovery. *See* Doc #2827 at 12-13 ("[D]iscovery is closed. It's been closed for a long time. That includes depositions.").

When the Court severed Giant Eagle from Track 1A in August of 2019, fact discovery regarding Giant Eagle was complete, Giant Eagle's expert reports were produced, Plaintiffs had deposed Giant Eagle's experts, and summary judgment motions and briefs by and against Giant Eagle were filed and pending.⁵ It would be unfairly prejudicial to Giant Eagle to now re-open discovery and other pre-trial proceedings just because Plaintiffs' dispensing amendments were allowed and then dismissed. The Sixth Circuit's recent Mandamus Opinion emphasized the importance of adhering to the Rules, including scheduling orders, and re-opening discovery in the distribution case would fly in the face of that ruling.

OBJECTIONS

Giant Eagle objects that Track 1A discovery closed long ago and it would be prejudicial and violate the Mandamus Opinion to re-open such discovery now. Plaintiffs should not be permitted to re-open such discovery and cure defects in their Track 1A distribution case. Plaintiffs had ample opportunity to pursue full discovery of Giant Eagle's pharmacists in Track 1A. Plaintiffs' strategic choices about the nature and extent of such discovery do not warrant a second bite at the apple. Instead, the Court should endorse the Special Master's prior ruling, which denied additional pharmacist depositions (Doc #2827). The disclosures provided herein by Giant Eagle are based upon the understanding that the factual record for the Track 1B trial

⁵ In Giant Eagle's Motion for Summary Judgment it argued that Plaintiffs failed to produce any expert report regarding Giant Eagle's alleged violation of the distribution regulations. *See* Doc #1759-3. Plaintiffs should not be permitted to retroactively cure that defect.

will be substantially the same as the record that was fully developed by the parties at the time Giant Eagle was severed in August of 2019, which does not include any discovery that occurred related to the now-dismissed Track 1B dispensing claims.

Giant Eagle further objects to the Order because it unfairly alters the more logical and balanced disclosure deadlines already set by the Court. *See* Doc #3234 (setting a deadline of October 14, 2020 for filing witness lists and a deadline of October 21, 2020 for objecting to a witness).

Giant Eagle further objects to the extent that the Order will provide Plaintiffs with an unfair opportunity to correct defects in their closed distribution case.

Giant Eagle further objects to the extent that the Court's Order purports to require Giant Eagle to prematurely make decisions about trial witnesses before knowing what witnesses Plaintiffs will call at trial.

Giant Eagle further objects that numerous Giant Eagle employees who have been disclosed in this matter and who may testify at trial have pharmacy degrees and pharmacy experience but are not currently store-level, practicing pharmacists and are instead serving in a management capacity. Giant Eagle interprets the Order to apply only to current store-level, practicing pharmacists and not to non-practicing pharmacists who service in a management capacity.

Giant Eagle further objects that in the event the Court rules that Plaintiffs may, over Giant Eagle's objection, introduce into evidence dispensing data or other dispensing-related information produced in connection with the now-dismissed dispensing claims, Giant Eagle may need to present additional testimony by more pharmacists.

Subject to and without waiving those objections, Giant Eagle makes the following disclosures in response to the Order.

Potential Practicing Pharmacist Trial Witnesses

At this time, subject to further pretrial and trial developments, which are presently unknown including possible rebuttal, Giant Eagle identifies the following practicing store-level pharmacists as those that it is most likely to call at trial:

Doug Holly, current Store #465, employed by Giant Eagle since 1999.

Holly Taylor, current Store #6376, employed by Giant Eagle since 2003, as a pharmacist since 2011.

Fred Weaver, current Store #6375, employed by Giant Eagle since 2000.

These store-level, practicing pharmacists will generally testify to the following subjects:

1. Giant Eagle's substantial compliance with the DEA Security Regulation at 21 C.F.R. §1301.71 (and similar Ohio regulations), including the subsidiary distributor-only SOM regulation at 21 C.F.R. §1301.74(b) and "Know Your Customer" policy, as evidenced by Giant Eagle's integrated internal control systems over its self-distribution operations and store-level ordering and dispensing, which prevent suspicious orders from being placed in the first instance. This topic will include a description of Giant Eagle's pharmacy-level ordering systems and potentially address any orders Plaintiffs claim are "suspicious."
2. Pharmacists' education, training, and experience, particularly with respect to: licensing and regulation by state and federal regulatory agencies including the DEA and Ohio Board of Pharmacy; the handling of controlled substances at the pharmacy level; compliance with applicable regulations including the placement of orders for

controlled substances; and the practice of pharmacy as part of their role in patient care.

3. Additional topics may be covered in rebuttal to Plaintiffs' case, including claims that Giant Eagle's pharmacists were improperly incentivized, improperly filled specific prescriptions, or otherwise contributed to the claimed public nuisance and/or conspired with suppliers.

These pharmacists are not being called by Giant Eagle to offer testimony about dispensing data or about any particular prescription except possibly to rebut such evidence offered by Plaintiffs or as reflected in Plaintiffs' own documents.

The above-described testimony is necessary in order to defend against Plaintiffs' distribution claim based upon Giant Eagle's alleged violation of the Security Regulation, including the SOM regulation. In order to fully explain how Giant Eagle's "overall security system," including its "system for monitoring the receipt, distribution and disposition of controlled substances" worked, testimony from store-level pharmacists who actually placed the orders to the HBC warehouse is required. Such testimony necessarily includes an explanation of the control systems in place at pharmacies to ensure that orders were appropriate and not "suspicious." Store-level pharmacists are in the best position to testify to these topics because of their personal knowledge and professional judgement insights. This testimony is highly relevant regardless of whether the testifying pharmacist was actually involved with a particular suspicious order because the Security Regulation and subsidiary SOM Regulation on their face require "effective controls and procedures to guard against theft and diversion." In addition, Plaintiffs insist on pursuing claims that directly implicate the intent and conduct of these pharmacists, who are the only witnesses that can directly refute such allegations.

Finally, with respect to whether Plaintiffs can also call pharmacists as witnesses, it is Giant Eagle's position that the answer depends upon whether Plaintiffs properly disclosed such witnesses during Track 1A discovery and other pretrial disclosures, including expert reports and witness lists, the personal knowledge of such witnesses, and the proffered relevance of such testimony.

Statement Regarding Corporate Entities

Giant Eagle, Inc. and its unincorporated warehouse division HBC Service Company ("HBC") may together be referred to during trial and on the verdict form as "Giant Eagle," with the understanding that, because original business records and witnesses refer to the HBC warehouse as HBC in order to distinguish it from Giant Eagle's grocery stores, pharmacies, and corporate offices, trial witnesses and exhibits may also identify the entity as HBC.

Dated: May 19, 2020

Respectfully submitted,

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